

IN THE CIRCUIT COURT FOR THE CITY OF ST. LOUIS
STATE OF MISSOURI

CADENCE COLLINS, individually and as Next Friend of her minor child K.H.,

Plaintiffs,

v.

MEAD JOHNSON & COMPANY, LLC,

Cause No.

SERVE: CSC-Lawyers Incorporating Service Company
221 Bolivar St.
Jefferson City, Missouri 65101

JURY TRIAL DEMANDED

and

MEAD JOHNSON NUTRITION COMPANY,

SERVE: CSC-Lawyers Incorporating Service Company
221 Bolivar St.
Jefferson City, Missouri 65101

and

JESSICA MACKEY
SERVE: Jessica Mackey
1044 Haversham Pl.
St. Louis, MO 63131

Defendants.

)

PETITION

Plaintiffs Cadence Collins, individually and as Next Friend of her minor child K.M., brings this Petition and Demand for Jury Trial (the "Petition") against Mead Johnson & Company, LLC,

Mead Johnson Nutrition Company (collectively, "Mead Johnson"), and Jessica Mackey (together with the Mead Johnson, "Defendants"). Plaintiffs allege the following upon personal knowledge as to Plaintiffs' own acts and experiences and upon information and belief, including investigation conducted by Plaintiffs' attorneys, as to all other matters:

NATURE OF THE ACTION

1. This action arises out of the injuries suffered by K.H. when, as a premature infant, she received Mead Johnson's cow's milk-based infant feeding products while at St. Louis Children's Hospital ("Childrens"). Mead Johnson's products caused K.H. to develop necrotizing enterocolitis ("NEC"), a life-altering and potentially deadly disease that largely affects premature babies who are given cow's milk-based feeding products. As a result, K.H. was seriously injured, resulting in long-term health effects.

2. Plaintiffs bring this cause of action against Defendants to recover for injuries that are the direct and proximate result of K.H. receiving Mead Johnson's unreasonably dangerous cow's milk-based infant feeding products.

PARTIES

3. Plaintiff Cadence Collins is a natural person and a resident of Illinois. Ms. Collins is the mother of Plaintiff K.H., a minor.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is in Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, are

manufacturers of cow's milk-based infant feeding products and market many of these products under the "Enfamil" brand name.

5. Defendant Jessica Mackey is a sales representative for Mead Johnson. Upon information and belief, she has served in this position since August 2018. Ms. Mackey is a natural person and resident of St. Louis, MO.

JURISDICTION AND VENUE

6. At all relevant times, Defendants had, and continue to have, regular and systematic contact with and conduct business in and from the State of Missouri, such that they have purposefully availed themselves of the laws of the State and expect to both sue and be sued in Missouri. In the alternative, Defendants' presence in the State of Missouri satisfies the due process requirements for Missouri courts to exercise jurisdiction over them. In the alternative, Defendants have consented to the exercise of jurisdiction over them by Missouri courts by registering and conducting business from the State of Missouri. In the alternative, Defendant Jessica Mackey resides in and is a citizen of the State of Missouri.

7. Missouri's general venue statute, Mo. Rev. Stat. § 508.010.4, provides as follows:

Notwithstanding any other provision of law, in all actions in which there is any count alleging a tort and in which the plaintiff was first injured in the state of Missouri, venue shall be in the county where the plaintiff was first injured by the acts or conduct alleged in the action.

8. Venue is proper in the Twenty-Second Judicial Circuit pursuant to Mo. Rev. Stat. § 508.010.4 because Plaintiff K.H. developed NEC after first being exposed to Mead Johnson's products while receiving care in St. Louis, Missouri.

FACTUAL ALLEGATIONS

K.H.'s NEC Diagnosis

9. K.H. was born prematurely at Barnes-Jewish Hospital in St. Louis, Missouri on September 4, 2021. She was 25 weeks and 3 days gestational age.

10. K.H. initially received human milk and human milk-based products. Notwithstanding that diet, K.H. was diagnosed with medical NEC on September 15, 2021. Fortunately, her medical NEC was able to be treated with antibiotics.

11. Following resolution of her medical NEC, K.H. was again fed a human milk diet, on which she remained healthy and was developing well.

12. K.H. reached 32 weeks gestational age on October 20, 2021. On or about that day, and notwithstanding her prematurity and previous diagnosis of medical NEC, she was transitioned to Enfamil formula.

13. Almost immediately, K.H. began to develop significant symptoms of NEC.

14. The disease progressed rapidly, and K.H. was required to undergo surgery on October 22, 2021. It was the first of multiple surgeries K.H. would be forced to endure as a result of NEC.

15. K.H.'s recurrent NEC was induced by Mead Johnson's formula. As a result of that formula feeding, K.H. suffered and continues to suffer from permanent and severe injuries.

Cow's Milk-Based Feeding Products Are Known To Cause NEC

16. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC

develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

17. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

18. For example, in one randomized, multicenter study of 926 preterm infants, NEC was **six to ten** times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and **three times** more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was **20 times more common** in those only fed cow's milk formula than in those fed breast milk.

19. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were **90% less likely** to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

20. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

21. A Surgeon General report, *The Surgeon General's Call to Action to Support Breastfeeding*, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are **138% more likely** to develop NEC.

22. The American Academy of Pediatrics, “an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults,” has advised that *all* premature infants should be fed either their mother’s milk or, if their mother’s milk is unavailable, pasteurized human donor milk. This recommendation is based on the “potent benefits of human milk,” including “lower rates of . . . NEC.”

23. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow’s milk-based formula suffered NEC **21% of the time.**

24. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow’s milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow’s milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives To Cow’s Milk-Based Products Exist

25. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother’s own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

26. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of

NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the benefits of a breast milk diet.

27. Mead Johnson's products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk has a lower risk profile for the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

28. For the above reasons, specialized experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

29. At the time K.H. received Mead Johnson's products, the science clearly demonstrated to Mead Johnson that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

30. Despite the scientific consensus among experts that Mead Johnson's cow's milk-based products present a dire threat to the health and development of preterm infants, Mead Johnson has made no changes to its products or the products' packaging, guidelines, instructions,

or warnings. Instead, Mead Johnson has continued to sell its unreasonably dangerous products to unsuspecting parents and to healthcare providers, generating huge profits as a result.

Mead Johnson's False And Misleading Marketing Regarding

Cow's Milk Based Infant Products

31. Mead Johnson has aggressively marketed its cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to K.H.'s birth.

32. Mead Johnson's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that Mead Johnson's cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. *None* of Mead Johnson's marketing materials, including its promotional websites, reference the science showing how significantly its products increase the risk of NEC.

33. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

34. Undoubtedly aware of the impact of its advertising, Mead Johnson, along with other formula manufacturers, are willing to spend massive sums to disseminate its message, with one study estimating that formula manufacturers collectively spent \$4.48 billion on marketing and promotion in 2014 alone.

35. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—

developed the International Code of Marketing of Breast-milk Substitutes (“the Code”), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

36. While Mead Johnson acknowledges the Code on its websites and claims to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, Mead Johnson’s aggressive marketing exploits new parents’ darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that its products come with a significantly increased risk of NEC.

37. Mead Johnson markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead Johnson emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the deficits and dangers that accompany its preterm products. For example, the since-edited webpage for Enfamil EnfaCare stated: “Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants” and noted that Enfamil formulas include “expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development.”

38. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive breast milk studies to date" (emphasis added).

39. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free formula, coupons, and even entire gift baskets to parents in hospitals, medical clinics, and residential charities where out-of-town families stay while their babies receive long-term treatment in the NICU.

40. Ms. Mackey was responsible for convincing hospital personnel, including personnel at the hospitals where K.H. was treated and developed NEC, to give Mead Johnson's products to infants and/or to convince parents like Cadence Collins to allow their children to be fed those products.

41. In connection with her job duties, Ms. Mackey provided information about Mead Johnson's products to hospital personnel, including personnel at the hospitals where K.H. was treated and developed NEC. Mead Johnson sales representatives, including Ms. Mackey, routinely misrepresented the risks and benefits of Mead Johnson's products versus human milk and human

milk products, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

42. Through Mead Johnson's early targeting, it creates brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use its term and toddler formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for Mead Johnson. Mead Johnson's gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their health care professionals, and they have been shown to negatively impact breastfeeding rates.

43. Further, upon recognition of a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Mead Johnson developed "Enfamil Human Milk Fortifier." This name is misleading in that it suggests that the product is derived from breast milk, when, in fact, it is a cow's milk-based product. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:



44. Mead Johnson has designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider Mead Johnson's cow's milk-based products to be a first choice. This marketing scheme is employed despite Mead Johnson knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like K.H..

Mead Johnson's Inadequate Warnings

45. Mead Johnson promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

46. The Enfamil products Mead Johnson markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

47. Despite knowing of the risk of NEC, the packaging of Mead Johnson's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead Johnson's products, or of the magnitude of this increased risk. Mead Johnson likewise did not provide instructions or guidance for how to avoid NEC.

48. Mead Johnson cites no medical literature or research to guide the use of its products.

49. Despite knowing of the risk of NEC, Mead Johnson did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead Johnson likewise did not provide instructions or guidance for how to avoid NEC.

50. Mead Johnson deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

51. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead Johnson failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Safer Alternative Designs

52. Mead Johnson's cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. Mead Johnson could have used pasteurized breast milk instead of cow's milk in its products, which would have produced a safer product.

53. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design

provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

54. On information and belief, Mead Johnson was aware of the significantly increased risk of NEC and death associated with its cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Mead Johnson has continued to use cow's milk as the foundation of its products.

COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Mead Johnson)

55. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

56. Mead Johnson, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute its products in a manner that was not unreasonably dangerous.

57. Mead Johnson also owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute its products in a manner that was merchantable and reasonably suited for their intended use.

58. Mead Johnson knew that its products would be used to feed premature infants like K.H. and knew (or reasonably should have known) that use of its cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, it continued to sell and market its defective products as appropriate for premature infants.

59. K.H. ingested Mead Johnson's unreasonably dangerous cow's milk-based formula. The risks of feeding that formula to K.H. outweighed the benefits. An ordinary consumer would

not expect Mead Johnson's products to carry a significant risk of serious injury and death from NEC.

60. Mead Johnson knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that Mead Johnson's products do.

61. Mead Johnson's products contained cow's milk at the time they left the manufacturing facility.

62. Mead Johnson did not develop a human-milk based product that was safer for premature infants and did not reformulate its products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

63. Mead Johnson's products were fed to K.H., which directly and proximately caused her NEC and led to injury and death.

WHEREFORE, Plaintiffs prays for judgment against Defendant Mead Johnson in an amount in excess of Twenty-Five Thousand Dollars (\$25,000) that is fair, just, and reasonable under the circumstances, for punitive damages, for pre- and post-judgment interest, for costs herein expended, and for such other relief as the Court deems just under the circumstances.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Mead Johnson)

64. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

65. Mead Johnson, as the manufacturer and/or seller of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of

its products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

66. Mead Johnson's duty to warn is part of its general duty to design, manufacture, and sell its infant products in a manner that is reasonably safe for their foreseeable uses. By designing its products with cow's milk-based ingredients, Mead Johnson undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

67. Specifically, Mead Johnson breached its duty to warn of the foreseeable risks of the infant products at issue in this litigation because it knew or should have known that its cow's milk-based premature infant products would be fed to premature infants like K.H., and that its products might cause those infants to develop NEC, severe injury, or death, yet it failed to provide adequate warnings of those risks. Among other risks, Mead Johnson:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like K.H.; and/or
- c. Inserted warnings and instructions on its products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

- d. Failed to insert a large and prominent “black box”-type warning that its cow’s milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow’s milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Mead Johnson’s products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow’s milk-based products.

68. Mead Johnson’s products contained cow’s milk at the time they left the manufacturing facility.

69. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Mead Johnson’s products, K.H. was fed cow’s milk-based products, which caused her to develop NEC.

70. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had Mead Johnson warned of the extreme risk associated with feeding premature infants cow’s milk-based formula, physicians and health care providers would not have fed the Injured Infant those products. Had Ms. Collins known of the significant risks of feeding K.H. cow’s milk-based formula, she would not have allowed such products to be fed to her child.

WHEREFORE, Plaintiffs pray for judgment against Defendant Mead Johnson in an amount in excess of Twenty-Five Thousand Dollars (\$25,000) that is fair, just, and reasonable under the circumstances, for punitive damages, for pre- and post-judgment interest, for costs herein expended, and for such other relief as the Court deems just under the circumstances.

COUNT III: NEGLIGENCE
(Against Mead Johnson and Jessica Mackey)

71. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

72. Mead Johnson as the manufacturer and/or seller of the products at issue in this litigation, and Ms. Mackey, as the sales representative promoting and educating hospitals and health care providers, including K.H.'s hospital and health care providers, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose, and warn the consuming public of any risks associated with Mead Johnson's products.

73. At all times relevant to this action, K.H.'s health care providers used the products at issue in their intended manner and for their intended purpose.

74. Mead Johnson, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached its duty to the general public and Plaintiffs. Ms. Mackey, directly or indirectly, negligently marketed, sold, and/or distributed Mead Johnson's cow's milk-based infant products at issue in this litigation, including to Ms. Collins and K.H.'s caregivers, and thereby breached her duty to the general public and the Plaintiffs.

75. Although Mead Johnson knew or reasonably should have known at the time of production that its cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, it failed to act in a reasonably prudent manner and breached its duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like K.H.; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that its cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Mead Johnson's products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or

- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

76. Ms. Mackey knew or reasonably should have known at the time of marketing, sale, and/or distribution of Mead Johnson's cow's milk-based infant products that they significantly increased the risk of NEC, serious injury, and death; she failed to act in a reasonably prudent manner and breached her duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like K.H.; and/or
- c. Failing to provide the hospitals for which she was Mead Johnson's sales representative, including K.H.'s treating hospitals, with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or
- d. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- e. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- f. Misrepresenting that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

77. In addition, although Mead Johnson knew or reasonably should have known at the time of production that its cow's milk-based products significantly increased the risk of NEC,

serious injury, and death, it failed to act in a reasonably prudent manner and breached its duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest its products.

78. As a direct and proximate result of Mead Johnson's and Ms. Mackey's failure to act in a reasonably prudent manner and their breach of duty, K.H. was fed cow's milk-based products, which caused her to develop NEC.

79. Had Mead Johnson and Ms. Mackey satisfied their duties to the consuming public in general, K.H. would not have been exposed to their unreasonably dangerous cow's milk-based products.

WHEREFORE, Plaintiffs pray for judgment against Defendant Mead Johnson in an amount in excess of Twenty-Five Thousand Dollars (\$25,000) that is fair, just, and reasonable under the circumstances, for punitive damages, for pre- and post-judgment interest, for costs herein expended, and for such other relief as the Court deems just under the circumstances.

COUNT IV: INTENTIONAL MISREPRESENTATION
(Against the Mead Johnson and Jessica Mackey)

80. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

81. At all times relevant to this action, K.H. (and Ms. Collins) used the products at issue in their intended manner and for their intended purpose.

82. Mead Johnson as the manufacturer and/or seller of the products at issue in this litigation, and Ms. Mackey, as the sales representative promoting and educating hospitals and health care providers, including K.H.'s hospital and health care providers, about the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular,

to provide truthful, accurate, fulsome information about the risks and benefits of using Mead Johnson's products when used in the intended manner and for the intended purpose.

83. Mead Johnson and Ms. Mackey breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

84. Specifically, upon information and belief, Mead Johnson and Ms. Mackey made the following false statements of material fact on an ongoing and repeated basis and prior to the time K.H. Huson was fed their products:

- a. That Mead Johnson's cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that Mead Johnson's products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That Mead Johnson's cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that Mead Johnson's products were not necessary to achieve adequate growth; and/or
- c. That Mead Johnson's products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That Mead Johnson's products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when,

in fact, the cow's milk in Mead Johnson's products was still capable of causing NEC, serious injury, and death; and/or

- h. That Mead Johnson's products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that Mead Johnson's products significantly increased the risk of NEC in premature infants.

85. Mead Johnson and Ms. Mackey knew or reasonably should have known those misrepresentations to be false.

86. Mead Johnson's and Ms. Mackey's misrepresentations were intended to, and in fact did, induce hospitals and health care providers, including K.H.'s hospital and health care providers, to provide their infant products to babies, including K.H..

87. Ms. Collins was not aware that these misrepresentations were false and justifiably relied on them. Mead Johnson's and Ms. Mackey's misrepresentations induced Ms. Collins and her health care providers to allow her child to be fed Mead Johnson's infant products, in reliance on all the messaging Ms. Collins received about formula feeding, including, directly or indirectly, Mead Johnson's and Ms. Mackey's messaging. Had Mead Johnson and Ms. Mackey not committed these intentional misrepresentations, K.H. would not have been exposed to the Mead Johnson's unreasonably dangerous cow's milk-based products.

88. As a direct and proximate result, Mead Johnson's products were fed to K.H., causing her NEC and subsequent injuries.

WHEREFORE, Plaintiffs pray for judgment against Defendant Mead Johnson in an amount in excess of Twenty-Five Thousand Dollars (\$25,000) that is fair, just, and reasonable

under the circumstances, for punitive damages, for pre- and post-judgment interest, for costs herein expended, and for such other relief as the Court deems just under the circumstances.

COUNT V: NEGLIGENT MISREPRESENTATION
(Against the Mead Johnson and Jessica Mackey)

89. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

90. At all times relevant to this action, K.H. used the products at issue in their intended manner and for their intended purpose.

91. Mead Johnson as the manufacturer and/or seller of the products at issue in this litigation, and Ms. Mackey, as the sales representative promoting and educating hospitals and health care providers, including K.H.'s hospital and health care providers, about the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful, accurate, and complete information about the risks and benefits of using Mead Johnson's products when used in the intended manner and for the intended purpose.

92. In the course of their business, Mead Johnson and Ms. Mackey breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

93. Specifically, upon information and belief, Mead Johnson made the following false statements of material fact on an ongoing and repeated basis and prior to the time K.H. was fed its products:

- a. That its cow's milk-based products were safe and beneficial for premature infants when it knew or should have known that its products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

- b. That its cow's milk-based products were necessary to the growth and nutrition of premature infants, when it knew or should have known that its products were not necessary to achieve adequate growth; and/or
- c. That its products have no serious side effects, when it knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That its products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in its products was still capable of causing NEC, serious injury, and death; and/or
- h. That its products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that its products significantly increased the risk of NEC in premature infants.

94. Upon information and belief, Ms. Mackey made the same false statements of material fact on an ongoing and repeated basis including to individuals at K.H.'s treating hospitals and prior to the time K.H. was fed Mead Johnson's products. Upon information and belief, Ms. Mackey also represented that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

95. Mead Johnson and Ms. Mackey were negligent or careless in not determining those representations to be false.

96. Mead Johnson's and Ms. Mackey's misrepresentations were intended to and did in fact induce hospitals and health care providers, including K.H.'s health care providers, to provide Mead Johnson's products to babies, including K.H..

97. Mead Johnson's and Ms. Mackey's misrepresentations induced, and were intended to induce, Ms. Collins to allow her child to be fed Mead Johnson's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, Mead Johnson's and Ms. Mackey's messaging. Had Mead Johnson and Ms. Mackey not committed these negligent misrepresentations, K.H. would not have been exposed to Mead Johnson's unreasonably dangerous cow's milk-based products.

98. As a direct and proximate result, Mead Johnson's products were fed to K.H., causing her NEC and subsequent injuries.

WHEREFORE, Plaintiffs pray for judgment against Defendant Mead Johnson in an amount in excess of Twenty-Five Thousand Dollars (\$25,000) that is fair, just, and reasonable under the circumstances, for punitive damages, for pre- and post-judgment interest, for costs herein expended, and for such other relief as the Court deems just under the circumstances.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

99. For compensatory damages in an amount to be proven at trial;

100. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Defendants' conduct;

101. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to

medical or mental health treatment which have or may be recommended;

102. For interest as permitted by law;
103. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and
104. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims triable.

Dated: June 14, 2024

Respectfully submitted,

/s/ John F. Garvey

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Attorneys for Plaintiff

Certificate of Filing

The undersigned hereby certifies that the foregoing Petition has been filed by using the Court's electronic case filing system on this 14th day of June, 2024.

/s/John F. Garvey _____